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XV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Separate Page)

A. General Provisions

Submitter: Richard Fisher, Selective Med Components, Inc., Mount Vernon, OH.
Phone: 740-397-7838. Registration No: 1528764
Contact Person: Richard Fisher
Classification: Class III.
Classification Name: Iontophoresis Device, 21 CFR 890.5525, Code EGJ
Common or usual name: Iontophoresis Device
Proprietary Name: Medion™ 6000 Series

B. Name of Predicate Devices

Iomed Phoresor II Model PM 900	K982668
Iomed Phoresor II Model PM 800	K933445*
R. A. Fischer MD-2 Iontophoresis Unit	K895365

C. Device Description:

The iontophoresis device is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes. The iontophoretic technology operates on the principle that an electic potential will cause ions in solution to migrate according to their electrical charges. Further, the quantity and distribution of a drug delivered into or across the skin by iontophoresis is dependent upon the charge and size (molecular weight) of the ion, strength of the electircal current being applied, electrode composition, duration of current flow and several other factors. The Medion™ is a battery-powered, solid state, microprocessor controlled device which controls current strength and duration, calculates total charge delivered and monitors current flow and electrode/tissue impedance.

D. Intended Use:

Intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes, as an alternative to hypodermic injection when it is advisable to avoid the pain that may accompany needle insertion and drug injection, and when it is advisable to minimize the infiltration of carrier fluids or to avoid the damage that may be caused by needle insertion when tissue is traumatized.

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E. Non-Clinical Test

Bench and other test data confirm that the electrical output of the Medion 6000 meets specifications fully, that the device operates as described above, and that it is substantially equivalent to the Phoresor 800 series (K934335).

F. Conclusions

The Medion 6000 is equivalent to the Phoresor[R] II, Model PM900 cleared in K982668, and to the Phoresor[R] II Model PM800 cleared in K933445 by Iomed, Inc. It is also equivalent to the MD-2 Iontophoresis Unit cleared by the R. A. Fischer Co., Inc., in K895365. However, it is more closely similar to the Phoresor units since the Fischer unit may deliver up to 20 mA of current. Therefore, the Medion™ is best compared to the Phoresor Model PM 800/900 units.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed. The decision tree appears in Appendix V.

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We believe we have provided sufficient information to allow the determination of substantial equivalence for this device. There are no specific guidance document on the subject but we have complied with all the terms of the general guidance documents for preparation of premarket notifications--510(k)s. If additional information or explanation is needed, please call me at 740-397-7838 or fax me at 740-397-6112. Alternately, you may contact Dr. H. N. Dunning at 301-229-2138, 8309 Bryant Dr., Bethesda, MD 20817.

Sincerely yours

Richard Fisher
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Mr. Richard Fisher
President
Selective Med Components, Inc.
6 Mechanic Street
Mt. Vernon, OH 43050

Re: K020476
Trade/Device Name: Medion 6000 Series
Regulation Number: 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: February 7, 2002
Received: February 12, 2002

Dear Mr. Fisher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milhem

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

XIII. Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Medion 6000 Series

Indications for Use:

Intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes, as an alternative to hypodermic injection when it is advisable to avoid the pain that may accompany needle insertion and drug injection, and when it is advisable to minimize the infiltration of carrier fluids or to avoid the damage that may be caused by needle insertion when tissue is traumatized.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ or Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020476

(Optional Format 1-2-96)